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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/160,076	09/24/98	SCOTT	D 308072000110

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EXAMINER	
WILSON, M	
ART UNIT	**PAPER NUMBER**
1633	26

DATE MAILED: 06/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Advisory Action

Application No.	Applicant(s)
09/160,076	Scott et al.
Examiner	**Art Unit**
Wilson, Michael C.	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *May 21, 2001* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *May 21, 2001*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);

   (b) ☐ they raise the issue of new matter. (See NOTE below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: *see attached*

4. ☐ Applicant's reply has overcome the following rejection(s):

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
   see attached

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: _____

   Claim(s) objected to: _____

   Claim(s) rejected: *31-51*

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

11. ☐ Other:

Deborah Clark

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The proposed limitation of a polypeptide selected from the group consisting of a mammalian antigenic polypeptide and an autoantigenic polypeptide (claim 52) would require an indefiniteness rejection because of the overlap between autoantigens and mammalian antigenic polypeptides. The scope of the proteins linked to the immunoglobulin has shifted to include mammalian antigenic polypeptides and would require a new consideration of the art. The limitation of an antigenic polypeptide of an allergen that has at least two epitopes would require a written description, new matter and enablement rejections and a new consideration of the art as it was not previously claimed or part of the disclosure as originally filed. The limitation of a bacculoviral vector (claim 57) would require a new consideration of the art and enablement as it was not previously claimed. The limitation of two or more copies of the sequence encoding the fusion protein operatively linked to a promoter (claim 58) would require a new consideration of the art and enablement as it was not previously claimed. The limitation of the placement of the N terminal region (claim 61) would require a new consideration of the art and enablement as it was not previously recited in the claims. The limitation of antigenic polypeptides of an allergen selected from the group consisting of a protein of pollen, a protein of ragweed and a protein of dust mite (claim 63) and ragweed antigen E (claim 64) would require a consideration of written description and art not previously required. The pharmaceutical compositions of claim 65-68 are new and would require considerations regarding enablement and art not previously required.

Applicants state Exhibit A lists the nucleotide sequences of various antigenic polypeptides. Exhibit A is a resume. A list of nucleic acid sequences encoding antigenic polypeptides known in

the art at the time of filing has been filed but does not indicate that such polypeptides are tolerogenic as claimed. Applicants argue that the specification provides adequate guidance to determine antigens to which tolerance is to be induced and cite page 11, lines 11-34. Applicants argument is not persuasive because the passage does not provide the specific parameters required to determine which antigens are tolerogenic. The declaration provided by Dr. Scott does not indicate that the experiments were performed prior to the filing of the instant application; therefore, the declaration does not indicate that applicants provided adequate written description of DNA encoding tolerogenic antigens. The declaration does not enable the instant invention because GAD, OVA, IRBP and insulin B chain residues are not contemplated in the instant invention or associated with autoimmune disease or allergic reactions. In paragraph 4, the example of the fusion protein encoding IgG and full length MBP, the declaration does not teach the IgG portion of the protein or how the fusion protein correlates to the fusion proteins in examples I-V in the specification. Therefore, the claims remain rejected under written description and enablement regarding DNA encoding tolerogenic antigens as claimed.

Applicants discussion of "autoantigens" is noted. The term is not enabled in the products claimed for reasons of record because the term is relative to the "host's tissues" as indicated in the definition provided which is not apparent from the claims or the specification.

Applicants arguments regarding indefiniteness rejections are noted but are directed toward the proposed claims which have not been entered. Therefore, applicants arguments are moot. The claims remain rejected under 112/2nd for reasons of record.

Applicants arguments regarding the art rejections are noted but are directed toward the proposed claims which have not been entered. Therefore, applicants arguments are moot. The claims remain rejected under 102 and 103 for reasons of record.

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